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EXTERNAL MEMORANDUM

TO: Chris Weis, U.S. EPA

FROM: Joyce Tsuji

DATE: September 28, 1999

CONTRACT: 8601184.001 0101

SUBJECT: Comments on Draft Bioavailability Quality Assurance Project Plan

This memo provides our comments on the Quality Assurance Project Plan for Vasquez Blvd-I70, Bioavailability of Arsenic in Site Soils using Juvenile Swine as an Animal Model (dated September 1999). Our comments for the most part relate to suggestions for more clarification rather than changes in the study design.

1. Page 3, last paragraph. In vitro solubility tests are stated to be experimental and therefore unsuitable for site-specific adjustments in bioavailability. First, please clarify whether this applies to in vitro testing in general or just this test for arsenic. The swine bioavailability test for arsenic is also somewhat experimental at this time. Perhaps it would be more accurate to just state that " EPA Region 8 does not currently accept the results of the in vitro solubility test for arsenic for setting a quantitative site-specific bioavailability adjustment."

2. Page 4, first paragraph, sixth sentence. Insert "in the gastrointestinal tract" after the word "solubility."

3. Page 8, second paragraph, item 4. Please clarify what is meant by "that collection of biological samples is random within the study design."

4. Page 10, B1 Sampling Process Design. We assume that the soil samples used will be sieved to <250 microns as you mentioned in the last meeting. The text of this document and the related Standard Operating Procedure (SOP) #6, however, do not mention this.

5. Page 12, first paragraph. Please consider taking a urine/fecal sample of all animals prior to the start of the dosing so that a baseline can be established for each animal. This will provide information on the differences in baseline urinary arsenic excretion among animals.

6. Page 16, fifth paragraph. The chemical and biological data are stated to be "screening-level preliminary data." This statement implies that the test and results are uncertain and that further studies will follow. Please provide further explanation.

7. The title page for SOP #1 implies that there will be a separate study protocol. Please clarify whether this will be the case.

8. SOP #6 states that the soil samples test will range in arsenic concentration from 200 to 2,000 ppm. I understand that the test requirements for adequate detection level and relatively low soil volume administered to the subjects result in needing higher arsenic soil concentrations; however, it would be best to use soils with arsenic levels near the lower end of this range, which would be closer to likely site action levels.

9. SOP #15 specifies that 200 arsenic-bearing particles be counted. Counting this many particles is particularly important if the samples have complex arsenic mineralogy.

10. On page 9 of SOP #15, no mention is made of quantitative analyses for perlite particles. Some quantitative analyses (e.g., on 10 particles/sample) would be helpful to better characterize this material. It would also be helpful to have a discussion in the SOP of what this material is expected to contain and what criteria will be used to identify it. Perlite may contain some characteristic stable compounds such as iron oxides (FeO[OH]) and cementite (Fe_3C).[1]

Please let me know if you should have any questions.

[1] Lewis, Richard J., Sr. 1997. Hawley's Condensed Chemical Dictionary. Thirteenth Edition. John Wiley & Sons. New York, NY.